510(k) Summary

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date:

APPLICANT RAY Co.,Ltd

ADDRESS #362-43 (218 Maeyoung St.) 3rd & 4th Floor,
Wonchun-dong, Youngtong-gu, Suwon-si, Gyeonggi-do, Korea

Manufacturer RAY Co.,Ltd
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Contact Person Yun Jung. HA
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Device Name

Trade/Proprietary Name : RAYSCAN α–Expert 3D

Common Name: Dental panoramic/tomography and cephalometric x-ray system

Classification

x-ray, tomography, computed, dental (21 CFR 892.1750)

Class : II

Product code : OAS

Panel : Radiology

Predicate device

Rotagraph EVO 3D(K111152)

Description

RAYSCAN α–Expert 3D is a 3D computed tomography for scanning hard tissues such as bones and teeth. By rotating the c-arm which includes the high voltage generator all-in-one x-ray tube and a detector on each end, CBCT image of whole dentomaxillofacial is attained by recombining data from the same level that are scanned from different angles.
Panoramic image scanning function for attaining images of the entire teeth and cephalometric scanning option for attaining the cephalic images are included.

The system includes processing, and archiving "SMARTDent "software(Optional)

Indication for use

RAYSCAN α–Expert 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images.
The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.
2D Image is obtained using the standard narrow beam technique.

"CAUTION: Federal (US) law restricts the sale of this device to, or on the order of, licensed professionals."

Statement of Substantial Equivalence

Parameter	RAYSCAN α–Expert 3D RAY Co.,Ltd	Rotograph EVO 3D K111152
Common Name	Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system
Indications for use	RAYSCAN α–Expert 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.2D Images are obtained using the standard narrow beam technique. "CAUTION: Federal (US) law restricts the sale of this device to, or on the order of, licensed professionals."	Rotograph EVO **3D**, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dentomaxillofacial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. 2D Images are obtained using the standard narrow beam technique. The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals.

Mode of Operation		Continuous operation with intermittent, stated permissible loading	Continuous operation with intermittent load
3D technology		CBCT Cone beam Computed Tomography	CBCT Cone beam Computed Tomography
Performance Specification		CBCT Computed tomography Panoramic Cephalometric(optional)	CBCT Computed tomography Panoramic Cephalostic(optional)
Exam mode	CT	Standard Implant Surgical guide Endo Sinus TMJ	Full Dentition Left Jaws Right Jaws Sinus
	PANO	Normal TMJ Sinus	Adult Panoramic Child Panoramic Open-closed mouth lateral TMJ P-A Sinus (rotational)
	Ceph	PA,AP Lateral SMV Carpus Reverse Town's Waters	Lateral Ceph A-P and P-A Ceph Carpus (hand)
	Other	-	Half Panoramic adult Half Panoramic child Orthogonal Projection Low Dose Panoramic Frontal Dentition
Detector Type		Computed Tomography(CT) : Flat panel X-ray sensor Pano : Flat panel X-ray sensor Ceph : Flat panel X-ray sensor	Computed Tomography(CT) : Flat panel X-ray sensor Pano : Flat panel X-ray sensor Ceph : CCD Sensor
Main Components		Ceph Apparatus	Ceph Apparatus
		Vertical Carriage	Vertical Carriage
		Rotator	Rotator
		X-RAY Generator	X-ray Generator
		X-ray tube	X-ray tube
		High Frequency Generator	High Frequency Generator
		Column	Column
		Touch monitor (panal)	Keyboard
		Detector(CT/Panoramic, Cephalometric)	Detector(CT/Panoramic, Cephalometric)
		Chinrest	Chinrest
		Head rest	Head rest
		Automatic Collimator	Collimator
		Exposure switch	Exposure switch
		Emergency stop switch	Emergency stop switch
Automatic Collimator		CT exams Panoramic exams Cephalometric exams	CT exams(Volumetric) Panoramic exams Cephalometric exams

Accessories	Bite block	Bite stick
	Chinrest(Patient support of the stand type) Chinrest(TMJ, Sinus and etc.)	Chinrest (Patient support of the stand type)
	Head rest	Head rest
	X-ray push button with extensible cable	X-ray push button with extensible cable
	Disposable byte protective sleeves	Disposable byte protective sleeves
	Remote controller	10ear centring pins for ceph
		10 disposable head strips for 3D exams
Display Type	TFT LCD type(Normally black) *1280x800 pixel	Alphanumeric"OLED"Display of 2 lines of 20 characters
	Touch monitor (panel).	Alpanumeric "OLED" Display.
	Exposure button.	x-ray push button with extensible cable.
	Operating PC screen.	Operating PC screen.
	Every operation is guided by messages shown on the display.	Every operation is guided by messages shown on the display.
	Selectable language : English	Selectable languages : Italian, English, French, Spanish, German, Turkish, Portuguese, Dutch.
	Operation S/W-RayScan(Workstation)	Operation S/W(Workstation)
Rated power	110-240 V~, 50 / 60 Hz, 2.5kVA	110-120/220-240V~,50/60Hz,1.5 kVA
Class	Class I with type B applied parts according to IEC 60601-1	Class I with type B applied parts according to IEC 60601-1
Focal size	0.5mm	0.5mm
Field of View(CT)	90x90mm	85x85mm
X-ray Voltage	60~90kVp	60~86kVp
X-ray Current	4~17mA	6~12 mA
Total Filtration	2.6 ㎜ Al equivalent	2.5 mm Al equivalent
Detector Pixel size	Computed Tomography(CT) : 100 ㎛ Pano : 100 ㎛ Ceph : 150 ㎛	Computed Tomography(CT) : 127 ㎛ Pano : 127 ㎛ Ceph : 48 ㎛
Magnification	CT : 1.39 Pano : 1.31 Ceph : 1.13	CT - Open/close mouth TMJ : 1.25 - Sinus : 1.27 Pano : 1.28 Ceph : 1.10 in the mid-sagittal plane in LL projection
Scan time	CT : 14sec Pano : 14sec Ceph : 0.3sec~3.0sec	CT : Max 20sec Pano : Max 13.8sec Ceph : 15sec
Grey level	CT : 14bit Pano : 14bit Ceph : 14bit	CT : 14bit Pano : 14bit Ceph : 12bit
Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Image acquisition	Giga-Ethernet Network	Giga-Ethernet Network
Rotation angle 3D	360°	200°

PC technical specifications	- OS : Windows 7, 32Bit - CPU : Intel Dual core and over - RAM : 4GB and over - HDD : 250GB and over - Network : Gigabit Ethernet - Resolution : 1366x768 and over	- OS : Windows 7, 32Bit - CPU: Intel® Core™ i5-750 - RAM: 4GB - HDD: 1TB - Network : Gigabit Ethernet - Resolution : 1440x900
Total Height	Max 2,296mm	Max 2,450mm
Weight	Computed Tomography(CT)+ Panoramic : 148kg(326lb) Computed Tomography(CT)+ Panoramic+Cephalostic(optional) : 165kg(363lb)	Computed Tomography(CT)+ Panoramic : 161kg(354lb) Computed Tomography(CT)+ Panoramic +Cephalostic(optional) : 186kg(409lb)
Type of installation	Wall or floor mount	Wall or floor mount
Patient position	Standing / Wheelchair	Standing / Wheelchair
Applicable Standards	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-3 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32 IEC 60601-2-44 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-3 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32 IEC 60601-2-44 IEC 60601-1-2
Certificate Product	CE0120(MDD93/42/EEC)	CE0051(MDD93/42/EEC), FDA

RAYSCAN α–Expert 3D has the same indication for use as the predicate devices.
It shares the same technological characteristics as the predicate devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device.

Safety and Effectiveness Information

Electrical, mechanical, environmental safety and performance testing according to standards IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32 and IEC 60601-2-44 was performed, and EMC testing was conducted in accordance with the standard IEC 60601-1-2.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" were performed.

All test results were satisfactory.

Conclusions

Based on a comparison of intended use, indications, constructions, construction materials, principal of Operation, features and technical data, the RAYSCAN α–Expert 3D system are safe and effective to perform its intended use as well as substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 12, 2013

Ray, Co., Ltd.
% Mr. Andrew Paeng
Consultant
8920 Wilshire Blvd., Suite 603
BEVERLY HILLS CA 90211

Re: K122981
Trade/Device Name: RAYSCAN α-Expert 3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: January 14, 2013
Received: February 06, 2013

Dear Mr. Paeng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: RAYSCAN α–Expert 3D

Indications For Use:

RAYSCAN α – Expert 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dentomaxillofacial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.

2D Image is obtained using the standard narrow beam technique.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

510(k): K122981